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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,849	11/13/2003	Charles M. Zepp	SEPR-P01-056	9511
28120 7590 01/23/2007 FISH & NEAVE IP GROUP ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			EXAMINER POLANSKY, GREGG	
			ART UNIT	PAPER NUMBER
			1609	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
31 DAYS		01/23/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/712,849

Applicant(s)

ZEPP ET AL.

Examiner

Gregg Polansky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: Notice of Restriction.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-3, 11-18, 20, 21, and 23-29, drawn to a method for preventing, reducing, or otherwise treating hearing impairment by administering a compound having a structure according to formula I in above referenced claims: classified in class 514 subclass 580, for example.
  - II. Claims 4-10, 18-20, 23-28, and 30 drawn to a method for preventing, reducing, or otherwise treating hearing impairment by administering a compound having a structure according to formula II in above referenced claims: classified in class 514 subclass 256, for example.
2. If Group I is chosen, a further restriction to one of the following sub-groups is required. This is NOT a species election.
  - Ia. Claims formula I wherein X represents C- R<sub>2</sub> and the variables R<sub>1</sub>, R<sub>2</sub> and R<sub>3</sub>, independently for each occurrence, represent hydrogen, alkyl, alkenyl, alkynyl, alkylthio, imine, amide, cyano, isocyano, carbonyl, carboxyl, carboxamide, alkylsulfonyl, arylsulfonyl, ketone, aldehyde, ester, heteroalkyl, nitrile, amidine, acetal, ketal, substituted or unsubstituted aryl, substituted or unsubstituted heteroaryl, aziridine, carbamate, imide, urea, or thiourea.

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- lb. Claims formula I where variables  $R_1$  and  $R_2$  taken together form a substituted or unsubstituted aryl, heteroaryl, carbocyclyl, or heterocyclyl ring (applicant may select one) having 4 to 8 members (applicant may select one), and  $R_3$  represents hydrogen, alkyl, alkenyl, alkynyl, alkylthio, imine, amide, cyano, isocyano, carbonyl, carboxyl, carboxamide, alkylsulfonyl, arylsulfonyl, ketone, aldehyde, ester, heteroalkyl, nitrile, amidine, acetal, ketal, substituted or unsubstituted aryl, substituted or unsubstituted heteroaryl, aziridine, carbamate, imide, urea, or thiourea.
- lc. Claims formula I where variables  $R_2$  and  $R_3$  taken together form a substituted or unsubstituted aryl, heteroaryl, carbocyclyl, or heterocyclyl ring (applicant may select one) having 4 to 8 members (applicant may select one), and  $R_1$  represents hydrogen, alkyl, alkenyl, alkynyl, alkylthio, imine, amide, cyano, isocyano, carbonyl, carboxyl, carboxamide, alkylsulfonyl, arylsulfonyl, ketone, aldehyde, ester, heteroalkyl, nitrile, amidine, acetal, ketal, substituted or unsubstituted aryl, substituted or unsubstituted heteroaryl, aziridine, carbamate, imide, urea, or thiourea.
3. If Group II is chosen, a further restriction to one of the following sub-groups is required. This is NOT a species election.
- IIa. Claims formula II wherein X represents C-  $R_2$  and the variables  $R_1$ ,  $R_2$  and  $R_3$ , independently for each occurrence, represent hydrogen, alkyl, alkenyl, alkynyl, alkylthio, imine, amide, cyano, isocyano, carbonyl, carboxyl, carboxamide, alkylsulfonyl, arylsulfonyl, ketone, aldehyde, ester,

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heteroalkyl, nitrile, amidine, acetal, ketal, substituted or unsubstituted aryl, substituted or unsubstituted heteroaryl, aziridine, carbamate, imide, urea, or thiourea.

IIb. Claims formula II wherein X represents C- R<sub>2</sub> and the variables R<sub>1</sub> and R<sub>2</sub> taken together form a substituted or unsubstituted aryl, heteroaryl, carbocyclyl, or heterocyclyl ring (applicant may select one) having either 4 to 8 members (applicant may select one), and R<sub>3</sub> represents hydrogen, alkyl, alkenyl, alkynyl, alkylthio, imine, amide, cyano, isocyano, carbonyl, carboxyl, carboxamide, alkylsulfonyl, arylsulfonyl, ketone, aldehyde, ester, heteroalkyl, nitrile, amidine, acetal, ketal, substituted or unsubstituted aryl, substituted or unsubstituted heteroaryl, aziridine, carbamate, imide, urea, or thiourea.

IIc. Claims formula II wherein X represents C- R<sub>2</sub> and the variables R<sub>2</sub> and R<sub>3</sub> taken together form a substituted or unsubstituted aryl, heteroaryl, carbocyclyl, or heterocyclyl ring (applicant may select one) having 4 to 8 members (applicant may select one), and R<sub>1</sub> represents hydrogen, alkyl, alkenyl, alkynyl, alkylthio, imine, amide, cyano, isocyano, carbonyl, carboxyl, carboxamide, alkylsulfonyl, arylsulfonyl, ketone, aldehyde, ester, heteroalkyl, nitrile, amidine, acetal, ketal, substituted or unsubstituted aryl, substituted or unsubstituted heteroaryl, aziridine, carbamate, imide, urea, or thiourea.

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- Ild. Sub-group IIa, IIb, or IIc wherein  $R_1$ ,  $R_2$  or  $R_3$  represents a sulfhydryl or alkylthio group.
- Ile. Claims formula II wherein X represents C-  $R_2$  and  $R_3$  represents a hydroxyl and  $R_1$  and  $R_2$  represents hydrogen, alkyl, alkenyl, alkynyl, alkylthio, imine, amide, cyano, isocyano, carbonyl, carboxyl, carboxamide, alkylsulfonyl, arylsulfonyl, ketone, aldehyde, ester, heteroalkyl, nitrile, amidine, acetal, ketal, substituted or unsubstituted aryl, substituted or unsubstituted heteroaryl, aziridine, carbamate, imide, urea, or thiourea, or  $R_1$ ,  $R_2$  taken together form a substituted or unsubstituted aryl, heteroaryl, carbocyclyl, or heterocyclyl ring (applicant may select one) having 4 to 8 members (applicant may select one).
- Ilf. Sub-group IIa, IIc, Ild, or Ile wherein at least one of  $R_1$  or  $R_2$  represents hydrogen.
- Ilg. Claims formula II wherein X represents C-  $R_2$ ,  $R_1$  or  $R_2$  represents lower straight-chained or branched  $C_1$  to  $C_6$  alkyls, and  $R_3$  represents hydrogen, alkyl, alkenyl, alkynyl, alkylthio, imine, amide, cyano, isocyano, carbonyl, carboxyl, carboxamide, alkylsulfonyl, arylsulfonyl, ketone, aldehyde, ester, heteroalkyl, nitrile, amidine, acetal, ketal, substituted or unsubstituted aryl, substituted or unsubstituted heteroaryl, aziridine, carbamate, imide, urea, thiourea, or sulfhydryl.
- IIh. Claims formula II wherein X represents C-H,  $R_1$  represents hydrogen and  $R_3$  represents a propyl group.

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Ili. Claims formula II wherein X represents C- R<sub>2</sub>, R<sub>2</sub> represents carboxyl or a pharmaceutically acceptable derivative thereof, and the variables R<sub>1</sub> and R<sub>3</sub>, independently for each occurrence, represent hydrogen, alkyl, alkenyl, alkynyl, alkylthio, imine, amide, cyano, isocyano, carbonyl, carboxyl, carboxamide, alkylsulfonyl, arylsulfonyl, ketone, aldehyde, ester, heteroalkyl, nitrile, amidine, acetal, ketal, substituted or unsubstituted aryl, substituted or unsubstituted heteroaryl, aziridine, carbamate, imide, urea, or thiourea.

4. The Applicant is required to elect a species to be examined. Where R<sub>1</sub>, R<sub>2</sub> or R<sub>3</sub> represent from the group of: hydrogen, alkyl, alkenyl, alkynyl, alkylthio, imine, amide, cyano, isocyano, carbonyl, carboxyl, carboxamide, alkylsulfonyl, arylsulfonyl, ketone, aldehyde, ester, heteroalkyl, nitrile, amidine, acetal, ketal, substituted or unsubstituted aryl, substituted or unsubstituted heteroaryl, aziridine, carbamate, imide, urea, or thiourea, applicant is required to elect a single species within the elected group. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations

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of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

The inventions are distinct, each from the other because of the following reasons:

5. Inventions I and II are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed (i.e., a method for preventing, reducing, or otherwise treating hearing impairment by administering a compound having a structure according to formula I; and a method for preventing, reducing, or otherwise treating hearing impairment by administering a compound having a structure according to formula II) have different classifications, use different core structures, and are mutually exclusive. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

6. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.




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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregg Polansky whose telephone number is (571) 272-9070. The examiner can normally be reached on M-F 7:30 A.M. - 5:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang or Cecilia Tsang, can be reached at (571) 272-0811 or (571) 272-0562, respectively. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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